

REMARKS

Claims 1-92 are pending. Claims 1-18, 23-29, 34, and 40-92 are withdrawn, and thus claims 19-22, 30-33, and 35-39 are currently examined.

Double Patenting Rejection Improper

Claims 19-22, 30-33, and 35-39 have been rejected under the judicially created doctrine of double patenting, based on a combination of three references: 1) commonly assigned U.S. Patent No. 6,537,520 to Rajopadhye, 2) U.S. Patent 5,679,318 to Vanderheyden (not commonly assigned), and 3) JP 56144060 to Nippon Oils and Fats Co. (not commonly assigned). Applicants submit that the rejection is improper.

As alluded to in the Office Action, the policy concern of a double patenting rejection lies in preventing an improper extension of a patent monopoly by filing multiple applications on obvious variations of the same invention. However, by the Examiner's own admission, this is not the case here. The Office Action clearly states, "Rajopadhye et al does not expressly teach stabilizers in the composition or kit." *Office Action at page 5, para. 10.* Thus, a proper double patenting rejection involving the Rajopadhye reference is impossible in the present case.

Obviousness Rejections Improper

Claims 19-22, 30-33, and 35-39 have been rejected as obvious under §103 over a combination of three references: 1) U.S. Patent No. 6,537,520 to Rajopadhye, 2) U.S. Patent 5,679,318 to Vanderheyden, and 3) JP 56144060 to Nippon Oils and Fats Co. Applicants submit that the rejection is improper.

The Examiner is respectfully reminded that references must come from analogous art - either the same area of art, i.e., pharmaceuticals, or one of which a person skilled in the art reasonably would be expected to be aware. Moreover, there must be a motivation or suggestion to combine the references, other than that provided by the Applicants' application.

A. The Nippon Oils And Fats Reference Is Not Analogous Art

The Nippon Oils and Fats reference relates to "[a]ntioxidant for feed use," which is clearly a reference to animal feed. This fact alone should be a concern, as the teachings of developments in goods for livestock consumption and pharmaceutical development would rarely seem to be relevant to one another. Apparently, Nippon Oils has found a combination which prevents oxidation "of the oil and fat in feed." As Applicants' application is not concerned with oxidation of oil and fat, Applicants submit that this development would not be something that a person of skill in the pharmaceutical art should be imputed to be aware of.

However, and assuming only for the sake of argument that the pharmaceutical and animal feed arts are sufficiently analogous, the Nippon Oils and Fats reference would still not support a finding of obviousness. Apparently, Nippon Oils has found that "[b]y combining L-ascorbic acid in gallic acid ... the antioxidising activity of gallic acid is synergically intensified," which prevents oxidation "of the oil and fat in feed." The portion of the disclosure provided to Applicants contains no suggestion that ascorbic acid is an optional component. Indeed, the synergistic result argues quite to the contrary. Thus, the Nippon Oils and Fats reference clearly **requires the presence of ascorbic acid**, which is not claimed by

the Applicants' independent claim. Therefore, the Applicants' claims are not rendered obvious even by the combination of references.

B. No Suggestion Or Motivation Exists to Combine The References

The Rajopadhye reference relates to peptide (or petidomimetic) targeting moiety that binds a receptor upregulated during angiogenesis. "Rajopadhye et al does not expressly teach stabilizers in the composition or kit." *Office Action at page 5, para. 10*. The Vanderheyden reference teaches that an antioxidant and human serum albumin make an excellent stabilizer for a therapeutic radionucleotide. Neither of these references suggest turning to means for preventing the oxidation of fats and oils in animal feed to supply their deficiencies. Nor does the Nippon Oils reference relate to radioactive elements, chelators, linking groups, etc. Thus, there is no permissible reason to combine the references.

Claims 19-22, 30-33, and 35-39 have been rejected as obvious under §103 over a combination of two references: 1) Bioconjugate Chemistry, Liu, S., 2001 12(4), 554-558, (published by the American Chemical Society), and 2) JP 56144060 to Nippon Oils and Fats Co. Applicants submit that the rejection is improper for the foregoing reasons relating to the Nippon Oils reference, as well as because the first reference, dated 2001, was clearly published after the filing date of the provisional application (Ser. No. 60/216,396) from which the present application claims priority, and thus is not prior art.

Claims 19-22, 30-33, and 35-39 have been rejected as obvious under §103 over a combination of three references: 1) U.S. Pat. No. 5,750,088 to Sworin et al. or U.S. Pat. No.

5,707,603 to Toner et al., 2) U.S. Patent 5,679,318 to Vanderheyden, and 3) JP 56144060 to Nippon Oils and Fats Co. As above, the Office Action states "[t]he primary references do not teach expressly adding stabilizers, such as gallic acid, in the radionuclide conjugate composition." *Office Action at page 6, para. 18.* Applicants submit that the rejection is improper.

A. The Nippon Oils And Fats Reference Is Not Analogous Art

As mentioned above, the Nippon Oils and Fats reference relates to "[a]ntioxidant for feed use." Nippon Oils has found a combination which prevents oxidation "of the oil and fat in feed." As Applicants' application is not concerned with oxidation of oil and fat, Applicants submit that this development would not be something that a person of skill in the pharmaceutical art should be imputed to be aware of.

Moreover, the Nippon Oils and Fats reference cannot not support a finding of obviousness. The portion of the disclosure provided to Applicants contains no suggestion that ascorbic acid is an optional component. Indeed, the stated synergistic result argues quite to the contrary. Thus, the Nippon Oils and Fats reference clearly **requires the presence of ascorbic acid**, which is not claimed by the Applicants' independent claim. Therefore, the Applicants' claims are not rendered obvious by the combination of references.

B. No Suggestion Or Motivation Exists to Combine The References

The Office Action states "[t]he primary references do not teach expressly adding stabilizers, such as gallic acid, in the radionuclide conjugate composition." *Office Action at page 6, para. 18.* The Vanderheyden reference teaches that an antioxidant and human serum

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albumin make an excellent stabilizer for a therapeutic radionucleotide. None of these references suggest turning to means for preventing the oxidation of fats and oils in animal feed to supply their deficiencies. Nor does the Nippon Oils reference relate to radioactive elements, chelators, linking groups, etc. Thus, there is no permissible reason to combine the references.

Applicants submit that the claims are in condition for allowance.

If the Examiner has any questions, the Examiner is cordially invited to call the undersigned.

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Brian J. Hubbard
Registration No. 45,873

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439